K031518

510(k) Summary

Date Prepared: May 14, 2003

Submitter: Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person: Dawn M. Stenstrom
Senior Regulatory Affairs Specialist

Phone: (763) 391-9604
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MAY 22 2003

Device Name and Classification:

Trade Name: EOPA CAP™ Elongated One-Piece Arterial Cannula with Pressure Monitoring Line
18, 20, 22, 24 Fr.

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: EOPA Elongated One-Piece Arterial Cannula and EOPA Elongated One-Piece Arterial Cannula with Guidewire
18, 20, 22, 24 Fr.
K031037

SELECT CAP™ Arterial Cannula with Pressure Monitoring Line
K010737

Device Description:
The EOPA CAP™ Elongated One-Piece Arterial Cannula with Pressure Monitoring Line is designed for use with cardiopulmonary bypass as an arterial return cannula. The pressure monitoring line allows measurement of central arterial pressure. The device is available in 18, 20, 22, and 24 Fr. diameters, with vented or non-vented caps. The device may also include Carmeda® coating.

Indication for Use
This product is intended for use with cardiopulmonary bypass as an arterial return cannula.

Comparison to Predicate Device
The predicate devices are cannulae with the same design characteristics. The predicate cannulae EOPA Elongated One-Piece Arterial Cannula has the same indications for use. The other predicate cannulae SELECT CAP Arterial Cannula features the same pressure monitoring line as the EOPA CAP.

Summary of Performance Data
In vitro visual, dimensional, simulated use and functional testing was used to establish the performance characteristic of the modifications of this device from previously marketed devices. In addition coverage, bio-activity and functional testing was performed on Carmeda® coated devices.

Conclusion
Medtronic Perfusion Systems has demonstrated that the EOPA CAP Elongated One-Piece Arterial Cannulae with pressure monitoring line are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Medtronic Perfusion Systems
c/o Ms. Dawn Stenstrom
Principal Regulatotry Affairs Specialist
7611 Northland Drive
Minneapolis, MN 55428

Re: K031518
EOPA Elongated One-Piece Arterial Cannula with Pressure Monitoring
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular
Regulatory Class: Class II (two)
Product Code: DWF
Dated: May 14, 2003
Received: May 15, 2003

Dear Ms. Stenstrom:

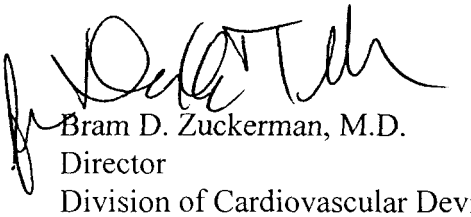
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031518

Device Name:

EOPA CAP™ Elongated One-Piece Arterial Cannula with Pressure Monitoring Line

Indications for Use:

These cannulae are intended for use with cardiopulmonary bypass as an arterial return cannula.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031518

(Optional Format 3-10-98)